

Notice of Allowability

Application No.

09/044,696

Applicant(s)

BARCHFELD ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 05/26/04.
2. ☒ The allowed claim(s) ~~is~~ are 19, 25-39 and 41-43, now renumbered as claims 1, 2-16 and 17-19 respectively.
3. ☒ The drawings filed on 25 April 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

ATTACHMENT TO NOTICE OF ALLOWABILITY

After-Final Amendment

1) Acknowledgment is made of Applicants' after-final amendment filed 05/26/04 in response to the final Office Action mailed 01/20/04 and the Advisory Action mailed 04/29/04. With this, Applicants amend the specification and drawings.

Examiner's Amendment

2) An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 C.F.R. 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee. The authorization for this Examiner's amendment was provided by Ms. Dahna Pasternak in a telephone interview on 09 June 2004. Ms. Pasternak instructed the Examiner to obtain the full citation of Giuliani *et al.* (recited on page 33 of the specification) from the IDS filed April 2003.

This application has been amended as indicated below:

- (a) In lines 1, 6 and 11 of page 26 of the specification, the recitation 'Squalene' is replaced with --SQUALENE--.
- (b) In lines 1, 6 and 11 of page 26 of the specification, the recitation 'Tween 80' is replaced with --TWEEN 80--.
- (c) In line 2 of page 26 of the specification, the recitation 'Span 85' is replaced with --SPAN 85--.
- (d) In line 26 of page 33 of the specification, replace the limitation 'in press' with --*J. Exp. Med.* 187: 1123-1132, 1998--.

Status of Claims

3) Claims 25-30, 37, 38, 39 and 41-43 have been amended via the amendment filed 05/26/04. Claims 19, 25-39 and 41-43 are pending and are under examination.

Substitute Sequence Listing

4) Acknowledgment is made of Applicants' substitute sequence listing filed 05/26/04, which has been entered.

Objection(s) Withdrawn

5) The objection to the specification made under 35 U.S.C. § 132 in paragraph 8 of the Office Action mailed 10/22/02 (paper no. 34) and maintained in paragraph 7 of the Office Action mailed 01/20/04 and paragraph 5 of the Advisory Action mailed 04/29/04 with regard to the addition of new matter to the specification, is withdrawn in light of Applicants amendments to the specification.

Rejection(s) Withdrawn

6) The rejection of claims 37-39 and 41-43 made in paragraph 12 of the Office Action mailed 01/20/04 and maintained in paragraph 9 of the Advisory Action mailed 04/29/04 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendments to the claims.

7) The rejection of claim 37 and 41-43 made in paragraphs 13(a) and 13(b) of the Office Action mailed 01/20/04 and maintained in paragraph 10 of the Advisory Action mailed 04/29/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claims.

8) The rejection of dependent claims 38 and 39 made in paragraph 13(d) of the Office Action mailed 01/20/04 and maintained in paragraph 11 of the Advisory Action mailed 04/29/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claims.

Remarks

9) Claims 19, 25-39 and 41-43, now renumbered as claims 1, 2-16 and 17-19 respectively, are allowed. The specific detoxified mutant 'LT-R72' in claim 19 (now renumbered as claim 1) is the *E. coli* ADP-ribosylating heat-labile toxin (LT) having Ala to Arg substitution at position 72 of the subunit A of LT, as described in the instant specification, and must be interpreted as such.

10) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission

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
of after-final amendments is (703) 872-9307.

11) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June, 2004


S. DEVI, PH.D.
PRIMARY EXAMINER